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BY: Rose A. Stowe DATE: August 13, 2003
Rose A. Stowe

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of	: Group Art Unit: 1617
	Bernd Fabry	:
Appln. No.:	09/554,387	: Examiner: Shaojia A.
		: Jiang, Ph.D.
Filed:	June 29, 2000	: Confirmation No.: 2050
		:
For:	HYPOCHOLESTEREMIC PREPARATIONS	: Attorney Docket
	CONTAINING MIXTURES OF PHYTO-	: No.: H 3185 US
	STENOL(ESTER)S AND CONJUGATED FATTY:	
	ACIDS, AND METHODS OF USING THE SAME:	

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. §1.193(b)

In response to the Examiner's Answer, mailed on June 18, 2003 (Paper No. 24), Appellant submits herewith a Reply Brief under 37 C.F.R. §1.193(b). This Reply Brief is being timely filed on or before August 18, 2003.

Appellant respectfully requests that the Board of Patent Appeals and Interferences, before making its decision on this appeal, consider the following rebuttals to statements made in the Examiner's Answer, as set forth below in detail.

REMARKS

Appellant respectfully disagrees with all of the Examiner's arguments and contentions advanced in Paper No. 24, for at least those reasons originally set forth in Appellant's Brief on Appeal. In this Reply Brief, Appellant would like to highlight for the Honorable Board three specific contentions/arguments made by the Examiner in Paper No. 24, which Appellant feels are most errant.

The Examiner's Assessment of the Summary of the Invention

First, in Paper No. 24, the Examiner insinuates that the Appellant's Summary of the Invention is less than correct. Appellant submits that the Summary of the Invention set forth in Appellant's Brief on Appeal is entirely correct. In Paper No. 24, the Examiner states:

"The summary of the invention contained in the brief is substantially correct. However, . . . Appellant's explanation of the data in Examples of the specification (see the last paragraph of Appellant's Summary of Invention, it is noted that this statement is not referred to the specification by page and line number)."
(See, Paper No. 24, ¶ 5).

Appellant respectfully submits that the Summary of the Invention portion of a Brief on Appeal need not refer to the Specification in every instance. In general, the concise explanation of the invention claimed must be supported by reference to the specification. (See, 37 C.F.R. §1.192). In the instant application on appeal, Appellant's Summary of the Invention makes frequent reference to the Specification. Appellant counts at least seven references to the Specification within the two pages summarizing the invention. Moreover, the portion of the Summary of the Invention which has been criticized by the Examiner (*i.e.*, the last paragraph of page 5 of Appellant's Brief on Appeal), is based upon Table 1 of the Specification which is cited elsewhere in the Summary, rudimentary mathematics, and basic logic. The lack of a specific reference to the Specification does not make the paragraph less correct.

In Appellant's Brief on Appeal, Appellant states, "[i]t should be noted in considering Appellant's Examples that the data represents the reduction of cholesterol relative to an initial 100%." (See, Appellant's Brief on Appeal, p. 5). Table 1 of the Specification clearly indicates that the figures are in terms of "[% rel]". The measured residual radiolabel

radioactivity is clearly the percentage remaining “relative” to the initial 100%. There is nothing incorrect about this statement. Appellant continues by stating, “[t]hus, a measurement of zero would indicate absolute removal of all blood cholesterol. In other words, lower numbers represent more removal of cholesterol and are better.” (*See, id.*). The measurements tabulated in the Specification are in terms of percentage remaining relative to the initial 100%. Thus, the lower the remaining percentage, the better the results. Again, nothing incorrect has been stated. Appellant continues by stating, “[w]hat should also be clearly understood, is that the removal of each additional amount of cholesterol becomes more difficult like any separation, for example reduction from 50% relative to initial level down to 49% relative to the initial level is more easily attained than reduction from 40% relative to initial levels down to 39% relative to the initial level.” (*See, id.*). There is no reference to the Specification for this statement. However, Appellant submits that this is a well understood phenomena related to separation or purification in general terms. In other words, as it is often said, 10% of the effort goes to removing the first 90% of a contaminant, and 90% of the effort goes to removing the last 10% of the contaminant. When discussing the removal of an undesirable component, it is understood that it is often more difficult to remove each additional amount from the source composition. Again, the lack of a specific reference to Appellant’s Specification does not make the statement any less true. Finally, Appellant attempts to offer a purely mathematical explanation in support of the preceding assessment by stating that, “[i]f one were to assume a linear reduction relationship, the reduction by one component of about 40% and another by 65%, would produce the conclusion that their combination must achieve 105% reduction. Clearly, such a result is not possible.” (*See, id.*). If a purely additive relationship were the correct way of interpreting such data then the result would be a reduction of 105% relative to the initial 100%. Again, this is clearly not possible, from a purely mathematical standpoint, and nothing untrue is seen in the statement made in the Brief on Appeal.

The Examiner's Misplaced Reliance on the Disclosure of Unsaturated Acids

Second, in Paper No. 24, the Examiner continues to insist that both the disclosure of linoleic acid and the disclosure of unsaturated fatty acids includes the disclosure of conjugated fatty acids. Appellant respectfully disagrees.

The Examiner argues that linoleic acid and conjugated linoleic acid are "structurally similar" and differ only in the placement of a carbon-carbon double bond. This statement may be technically correct, but it simply does not appreciate the differences between unsaturated fatty acids and conjugated fatty acids. The statement advanced by the Examiner is no more correct than arguing that an alcohol is "structurally similar" to a carboxylic acid and differs only in the replacement of two hydrogens with a double-bonded oxygen atom. Just as the properties and reactivity of alcohols and carboxylates differ, so to do the properties and reactivity of conjugated acids and nonconjugated acids. Conjugation renders multiple unsaturations more stable. There is a π -bonding structure associated with conjugation which is not present in an otherwise polyunsaturated compound.

Furthermore, conjugated linoleic acid is obtained from entirely different sources than linoleic acid. Disclosure of linoleic acid would not motivate one of ordinary skill in the art to seek out and employ conjugated linoleic acid. Conjugated linoleic acid can be obtained from the meat and milk of ruminant animals whose guts enzymatically convert linoleic acid to conjugated linoleic acid, or linoleic acid can be subjected to harsh chemical modification to bring about conjugation. However, there is nothing that would cause one of ordinary skill in the art to consider linoleic acid and conjugated linoleic acid to be interchangeable.

The Examiner's Misunderstanding of the Evidence of Unexpected Results

Third, the Examiner continues to criticize the evidence of unexpected results set forth in Appellant's Specification. In Paper No. 24, the Examiner again argues that "lauric acid in lauric acid β -sitostanol ester or lauric acid β -sitostenol ester employed in the testing herein is not even an unsaturated carboxylic acid (having no double bond), which is not the instant preferred carboxylic acid having up to 3 double bonds (see claims 13-14 herein)." (See, Paper No. 24, p. 11). This statement only serves to underscore the Examiner's lack of understanding of

the invention. The lauric acid esters of β -sitostenol and β -sitostanol listed in Table 1 are examples of component (a) of the claimed invention and are combined with conjugated linoleic acid (component (b)) in a mixture of the two components. There is no requirement in the claimed invention that the acid moiety of the phytostenol ester be unsaturated. In fact, component (a) need not even be an ester, but may be selected from phytostenol or phytostenol esters.

As pointed out by Appellant in Appellant's Brief on Appeal, in Appellant's Request for Reconsideration After Final and in Appellant's Response to Paper No. 12, the lauric acid sitostenol **esters** listed in Table 1 of the Specification are **phytostenol esters** and their combination as a mixture with conjugated linoleic acid is most certainly within the scope of the present invention. (*See, e.g.*, Appellant's Brief on Appeal, p. 14; Appellant's Request for Reconsideration After Final, p. 7; & Appellant's Response to Paper No. 12, p. 6).

Moreover, the Examiner continues to criticize the evidence because there is no side-by-side comparison. Appellant has repeatedly pointed out to the Examiner that Section 716 of the M.P.E.P. does **not** require the submission of a "side-by-side" comparison in order to successfully establish unexpected results. Appellant has pointed out that section 716.02(e) simply outlines one requirement of a Declaration under 37 C.F.R. §1.132, namely that such a declaration compare the claimed subject matter with the closest prior art available.

The prior art does not disclose a combination of at least one component (a) selected from the group consisting of phytostenols and phytostenol esters and at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms. Requiring a comparison of the invention to a combination of a phytostenol compound and a conjugated acid would require a comparison of the invention to the invention.

As explained in Appellant's Brief on Appeal, the claimed compositions exhibit a synergistic reduction in serum cholesterol levels. The evidence set forth in Appellant's Specification is sufficient to rebut any alleged *prima facie* case of obviousness.

CONCLUSION

Appellant respectfully requests that the Honorable Board consider the rebuttals presented above, and find for Appellant, reversing the Examiner's final rejection.

Respectfully submitted,

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August 13, 2003
(Date)

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